Exhibit 11

***United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS**

Exhibit to the August 28, 2009 Declaration of Sarah L. Reid In Support of Defendants' Common Opposition to Plaintiffs' Motion for Partial Summary Judgment

15 of 16 DOCUMENTS

*** ARCHIVE MATERIAL ***

*** CURRENT THROUGH 108TH CONGRESS, 1ST SESSION ***

TITLE 42. THE PUBLIC HEALTH AND WELFARE
CHAPTER 7. SOCIAL SECURITY ACT
TITLE XIX. GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

42 USCS § 1396r-8 (2003)

§ 1396r-8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement.

(1) In general. In order for payment to be available under section 1903(a) [*42 USCS § 1396b*(a)] or under part B of title XVIII [*42 USCS §§ 1395j* et seq.] for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of title VI of the Veterans Health Care Act of 1992 [enacted Nov. 4, 1992]) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) Effective date. Paragraph (1) shall first apply to drugs dispensed under this title [*42 USCS §§ 1396* et seq.] on or after January 1, 1991.

(3) Authorizing payment for drugs not covered under rebate agreements. Paragraph (1), and section 1903(i)(10)(A) [*42 USCS § 1396b*(i)(10)(A)], shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) Effect on existing agreements. In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section [Nov. 5, 1990], such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title [*42 USCS §§ 1396* et seq.]. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section [enacted Nov. 5, 1990] provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) Limitation on prices of drugs purchased by covered entities.

(A) Agreement with Secretary. A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service Act [*42 USCS § 256b]* with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph.

(B) Covered entity defined. In this subsection, the term "covered entity" means an entity described in section 340B(a)(4) of the Public Health Service Act [*42 USCS § 256b*(a)(4)].

(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates. If the Secretary does not establish a mechanism under section 340B(a)(5)(A) of the Public Health Service Act [*42 USCS § 256b*(a)(5)(A)] within 12 months of the date of the enactment of such section [enacted Nov. 4, 1992], the following requirements shall apply:

(i) Entities. Each covered entity shall inform the single State agency under section 1902(a)(5) [*42 USCS § 1396a*(a)(5)] when it is seeking reimbursement from the State plan for medical assistance described in section 1905(a)(12) [*42 USCS § 1396d*(a)(12)] with respect to a unit of any covered outpatient drug which is subject to an agreement under section 340B(a) of such Act [*42 USCS § 256b*(a)].

(ii) State agency. Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 340B of such Act [*42 USCS § 256b]*, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

(D) Effect of subsequent amendments. In determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act [*42 USCS § 256b]*, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992 [enacted Nov. 4, 1992].

(E) Determination of compliance. A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 340B of the Public Health Service Act [*42 USCS § 256b]* (as in effect immediately after the enactment of this paragraph [enacted Nov. 4, 1992]) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(6) Requirements relating to master agreements for drugs procured by department of veterans affairs and certain other Federal agencies.

(A) In general. A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, United States Code, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) Effect of subsequent amendments. In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, United States Code, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992 [enacted Nov. 4, 1992].

(C) Determination of compliance. A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, United States Code (as in effect immediately after the enactment of this paragraph) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(b) Terms of rebate agreement.

(1) Periodic rebates.

(A) In general. A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title [*42 USCS §§ 1396* et seq.], a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) Offset against medical assistance. Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1) [*42 USCS § 1396b*(a)(1)].

(2) State provision of information.

(A) State responsibility. Each State agency under this title [*42 USCS §§ 1396* et seq.] shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

(B) Audits. A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) Manufacturer provision of price information.

(A) In general. Each manufacturer with an agreement in effect under this section shall report to the Secretary--

(i) not later than 30 days after the last day of each rebate period under the agreement (beginning on or after January 1, 1991), on the average manufacturer price (as defined in subsection (k)(1)) and, (for single source drugs and innovator multiple source drugs), the manufacturer's best price (as defined in subsection (c)(2)(B)) for covered outpatient drugs for the rebate period under the agreement[,];

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990[,] for each of the manufacturer's covered outpatient drugs; and

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)--

(I) the manufacturer's average sales price (as defined in section 1847A(c) [*42 USCS § 1395w-3a*(c)]) and the total number of units specified under section 1847A(b)(2)(A) [*42 USCS § 1395w-3a*(b)(2)(A)];

(II) if required to make payment under section 1847A [*42 USCS § 1395w-3a],* the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B) [*42 USCS § 1395w-3a*(c)(2)(B)]; for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) [*42 USCS § 1395u*(o)(1)] or section 1881(b)(13)(A)(ii) [*42 USCS § 1395rr*(b)(13)(A)(ii)].

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services.

(B) Verification surveys of average manufacturer price and manufacturer's average sales price. The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $ 100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A [*42 USCS § 1320a-7a]* (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a*(a)].

(C) Penalties.

(i) Failure to provide timely information. In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $ 10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of the 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) False information. Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $ 100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A [*42 USCS § 1320a-7a]* (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [*42 USCS § 1320a-7a*(a)].

(D) Confidentiality of information. Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) (other than the wholesale acquisition cost for purposes of carrying out section 1847A [*42 USCS § 1395w-3a])* is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State

agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except--

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1847A [*42 USCS § 1395w-3a]* (including the determination and implementation of the payment amount), or to carry out section 1847B [*42 USCS § 1395w-3b]*,

(ii) to permit the Comptroller General to review the information provided, and

(iii) to permit the Director of the Congressional Budget Office to review the information provided.

The previous sentence shall also apply to information disclosed under section 1860D-2(d)(2) or 1860D-4(c)(2)(E) [*42 USCS § 1395w*-102(d)(2) or 1395w-104(c)(2)(E)] and drug pricing data reported under the first sentence of section 1860D-31(i)(1) [*42 USCS § 1395w*-141(i)(1)].

(4) Length of agreement.

(A) In general. A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) Termination.

(i) By the Secretary. The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) By a manufacturer. A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) Effectiveness of termination. Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) Notice to States. In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) Application to terminations of other agreements. The provisions of this subparagraph shall apply to the terminations of agreements described in section 340B(a)(1) of the Public Health Service Act [*42 USCS § 256b*(a)(1)] and master agreements described in section 8126(a) of title 38, United States Code.

(C) Delay before reentry. In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) Determination of amount of rebate.

(1) Basic rebate for single source drugs and innovator multiple source drugs.

(A) In general. Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of--

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of--

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

(B) Range of rebates required.

(i) Minimum rebate percentage. For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning--

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; and

(V) after December 31, 1995, is 15.1 percent.

(ii) Temporary limitation on maximum rebate amount. In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning--

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(C) Best price defined. For purposes of this section--

(i) In general. The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding--

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act [*42 USCS § 256b*(a)(4)(L)]);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D-31 [*42 USCS § 1395w*-141]; and

(VI) [Caution: This subclause applies to prices charged for drugs dispensed on or after January 1, 2006, as provided by § 103(e)(2) of Act Dec. 8, 2003, P.L. 108-173, which appears as a note to this section.] any prices charged which are negotiated by a prescription drug plan under part D of title XVIII [*42 USCS §§ 1395w*-101 et seq.], by an MA-PD plan under part C of such title [*42 USCS §§ 1395w-21* et seq.] with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2) [*42 USCS § 1395w*-132(a)(2)]) with respect to such drugs on behalf of individuals entitled to benefits under part A [*42 USCS §§ 1395c* et seq.] or enrolled under part B of such title [*42 USCS §§ 1395j* et seq.].

(ii) Special rules. The term "best price"--

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and

(III) shall not take into account prices that are merely nominal in amount.

(iii) Application of auditing and recordkeeping requirements. With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act [*42 USCS § 256b*(a)(4)(L)], any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act [*42 USCS § 256b*(a)(5)(C)].

(2) Additional rebate for single source and innovator multiple source drugs.

(A) In general. The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of--

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which--

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) Treatment of subsequently approved drugs. In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

(3) Rebate for other drugs.

(A) In general. The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of--

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) Applicable percentage defined. For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning--

(i) before January 1, 1994, is 10 percent, and

(ii) after December 31, 1993, is 11 percent.

(d) Limitations on coverage of drugs.

(1) Permissible restrictions.

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction. The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Agents when used to promote smoking cessation.

(F) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(G) Nonprescription drugs.

(H) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(I) Barbiturates.

(J) Benzodiazepines.

(3) Update of drug listings. The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies. A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act [*21 USCS §§ 301* et seq.] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs. A State plan under this title [*42 USCS §§ 1396* et seq.] may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval--

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions. A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this Act [*42 USCS §§ 301* et seq.].

(e) Treatment of pharmacy reimbursement limits.

(1) In general. During the period beginning on January 1, 1991, and ending on December 31, 1994--

(A) a State may not reduce the payment limits established by regulation under this title or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) Special rule. If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) Effect on State maximum allowable cost limitations. This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

[(4)] Establishment of upper payment limits. The Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(f) (1) [Deleted]

(2) [Redesignated]

(g) Drug use review.

(1) In general.

(A) In order to meet the requirement of section 1903(i)(10)(B) [*42 USCS § 1396b*(i)(10)(B)], a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess date on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information; and

(III) the DRUGDEX Information System; and

(IV) [Deleted]

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1903 [*42 USCS § 1396b]*, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1919 [*42 USCS § 1396r]*, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) Description of program. Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) Prospective drug review.

(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this title [*42 USCS §§ 1396* et seq.], typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this title [*42 USCS §§ 1396* et seq.] by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this title [*42 USCS §§ 1396* et seq.] or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title [*42 USCS §§ 1396* et seq.]:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title [*42 USCS §§ 1396* et seq.] or caregiver of such individual refuses such consultation.

(B) Retrospective drug use review. The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r) [*42 USCS § 1396b*(r)]) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this title [*42 USCS §§ 1396* et seq.], or associated with specific drugs or groups of drugs.

(C) Application of standards. The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection [paragraph] (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, in-

troduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) Educational program. The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) State drug use review board.

(A) Establishment. Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the "DUR Board") either directly or through a contract with a private organization.

(B) Membership. The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

(i) The clinically appropriate prescribing of covered outpatient drugs.

(ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.

(iii) Drug use review, evaluation, and intervention.

(iv) Medical quality assurance. The membership of the DUR Board shall be made up at least 1/3 but no more than 51 percent licensed and actively practicing physicians and at least 1/3 [* * *] licensed and actively practicing pharmacists.

(C) Activities. The activities of the DUR Board shall include but not be limited to the following:

(i) Retrospective DUR as defined in section [paragraph] (2)(B).

(ii) Application of standards as defined in section [paragraph] (2)(C).

(iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) Annual report. Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) Electronic claims management.

(1) In general. In accordance with chapter 35 of title 44, United States Code [*44 USCS §§ 3501* et seq.] (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title [*42 USCS §§ 1396* et seq.], a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) Encouragement. In order to carry out paragraph (1)--

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1903(a)(3)(A)(i) [*42 USCS § 1396b*(a)(3)(A)(i)] (at a matching rate of 90 percent) if the State acquires, through appli-

cable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) Annual report.

(1) In general. Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

(2) Details. Each report shall include information on--

(A) ingredient costs paid under this title [*42 USCS §§ 1396* et seq.] for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

(B) the total value of rebates received and number of manufacturers providing such rebates;

(C) how the size of such rebates compare with the size or [of] rebates offered to other purchasers of covered outpatient drugs;

(D) the effect of inflation on the value of rebates required under this section;

(E) trends in prices paid under this title [*42 USCS §§ 1396* et seq.] for covered outpatient drugs; and

(F) Federal and State administrative costs associated with compliance with the provisions of this title [*42 USCS §§ 1396* et seq.].

(j) Exemption of organized health care settings.

(1) Covered outpatient drugs dispensed by health maintenance organizations, including medicaid managed care organizations that contract under section 1903(m) [*42 USCS § 1396b*(m)], are not subject to the requirements of this section.

(2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.

(3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).

(k) Definitions. In this section--

(1) Average manufacturer price. The term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.

(2) Covered outpatient drug. Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means--

(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12) [*42 USCS § 1396d*(a)(12)], a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and--

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act [*21 USCS § 355* or former 357] or which is approved under section 505(j) of such Act [*21 USCS § 355*(j)];

(ii) (I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 [enacted Oct. 10, 1962] or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [*21 USCS § 321*(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [*21 USCS § 331*, 332(a), or 334(a)] to enforce section 502(f) or 505(a) of such Act [*21 USCS § 352*(f) or 355(a)]; or

(iii) (I) which is described in section 107(c)(3) of the Drug Amendments of 1962 [*21 USCS § 321* note] and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food,

Drug, and Cosmetic Act [*21 USCS § 355*(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which--

(i) may only be dispensed upon prescription,

(ii) is licensed under section 351 of the Public Health Service Act [*42 USCS § 262]*, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [*42 USCS § 356]*.

(3) Limiting definition. The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title [*42 USCS §§ 1396* et seq.] as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological [product] used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

(4) Nonprescription drugs. If a State plan for medical assistance under this title [*42 USCS §§ 1396* et seq.] includes coverage of prescribed drugs as described in section 1905(a)(12) [*42 USCS § 1396d*(a)(12)] and permits coverage of drugs which may be sold without a prescription (commonly referred to as "over-the-counter" drugs), if they are prescribed by a physician (or other person authorized to prescribe under State law), such a drug shall be regarded as a covered outpatient drug.

(5) Manufacturer. The term "manufacturer" means any entity which is engaged in--

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Medically accepted indication. The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [*21 USCS §§ 301* et seq.] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

(7) Multiple source drug; innovator multiple source drug; noninnovator multiple source drug; single source drug.

(A) Defined.

(i) Multiple source drug. The term "multiple source drug" means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there are 2 or more drug products which--

(I) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations"),

(II) except as provided in subparagraph (B), are pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the State during the period.

(ii) Innovator multiple source drug. The term "innovator multiple source drug" means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) Noninnovator multiple source drug. The term "noninnovator multiple source drug" means a multiple source drug that is not an innovator multiple source drug.

(iv) Single source drug. The term "single source drug" means a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(B) Exception. Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) Definitions. For purposes of this paragraph--

(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity;

(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence; and

(iii) a drug product is considered to be sold or marketed in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in that State.

(8) Rebate period. The term "rebate period" means, with respect to an agreement under subsection (a), a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) State agency. The term "State agency" means the agency designated under section 1902(a)(5) [*42 USCS § 1396a*(a)(5)] to administer or supervise the administration of the State plan for medical assistance.